DEC 3 0 2003

VARIAN
medical systems

Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304-1038
USA
tel +1 650 493 4000
www.varian.com

510(k) Summary

K033339 P.1/2

The following information is provided following the format of 21 CFR 807.92 for the Acuity with Conebeam Computed Tomography

1. **Submitter:** Varian Medical Systems
   3100 Hansen Way M/S H055
   Palo Alto, CA 94304-1129
   Contact Name: Vy Tran
   Phone: (650) 424-5731
   Fax: (650) 842-5040
   Email: vy.tran@varian.com
   Date summary was prepared: October 16, 2003

2. **Name of the Device:** Acuity with Conebeam Computed Tomography
   Trade/Proprietary Name: Acuity with Conebeam Computed Tomography
   Common or Usual Name: Acuity CBCT
   Classification Name: Stationary x-ray system
   21 CFR §892.1680
   Class II
   Product Code: KPR

3. **Predicate Devices to claim substantial equivalence:**
   a. Acuity Radiation Therapy Simulator, K023052
   b. Ximatron Scanvision, K981056

4. **Description of the Device:** Acuity with ConeBeam Computed Tomography (CBCT) is intended to assist the Radiation Oncologist in acquiring 3D multislice planning data in patient set-ups where conventional (Computerized Tomography) CT imaging is not possible. CBCT is a new feature to the Varian Medical Systems Radiation Therapy Simulator, "Acuity" (K023052), and acquires CT slice information as digital images from the Acuity simulator. The images can be viewed and manipulated directly on a computer screen and placed into the Vision Image database for the purpose of radiation therapy treatment planning and patient positioning. CBCT provides Acuity the capability of acquiring and reconstructing 15-17cm of volumetric data in one gantry rotation. This represents approximately 340 0.5mm slices. Acuity combines conventional and CT simulation into one product. Acuity can change from radiographic and fluoroscopic mode for isocenter localization to CT acquisition mode for treatment planning. This is accomplished with no movement of the patient from the actual treatment position.

K033339 , p2 of 2

5. **Intended Use Statement:** The Acuity Radiation Therapy Simulator is to be used in radiation therapy simulation, using a fluoroscopic and/or radiographic x-ray system for visualizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irridation field to be applied. The Acuity ConeBeam Computed Tomography (CBCT) is intended to assist the Radiation Oncologist in acquiring 3D "multislice" planning data in patient set-ups for the purpose of radiation therapy treatment planning and patient positioning.

6. **Summary of the Technological Characteristics:** the Acuity Radiation Therapy Simulator, K023052 has been modified to include Conebeam Computerized Tomography as a new feature. This new feature will allow the Acuity Radiation Therapy Simulator to acquire 3D multi-slice planning data in patient set-ups for the purpose of radiation therapy treatment planning and patient positioning which is substantially equivalent to the Varian Medical Systems Scanvision device, K981056. The substantial equivalence comparison chart provides a comparison of the technological characteristics to those of the predicate devices. The chart is located in Tab G.

7. **Performance Standards** – Acuity with Conebeam Computed Tomography was tested in accordance with 21 CFR§1020 - Performance standards for ionizing radiation emitting products. Specifically §1020.30 - Diagnostic x-ray systems and their major components and §1020.33 - Computed tomography (CT) equipment. The results of the tests demonstrated that the Acuity CBCT met the performance standards requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2003

Mr. Vy Tran
Corporate Director, Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K033339
Trade/Device Name: Acuity with ConeBeam Computerized Tomography
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: 90 KPQ
Dated: October 16, 2003
Received: October 17, 2003

Dear Mr. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033339
Device Name: Acuity with Conebeam Computed Tomography

Indications For Use:

The Acuity Radiation Therapy Simulator is to be used in radiation therapy simulation, using a fluoroscopic and/or radiographic x-ray system for visualizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irridation field to be applied. The Acuity ConeBeam Computed Tomography (CBCT) is intended to assist the Radiation Oncologist in acquiring 3D "multislice" planning data in patient set-ups for the purpose of radiation therapy treatment planning and patient positioning.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

David G. Seyman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033339